



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|--|-----------------------------------|-----------------------------|
| 10/531,769 | 12/14/2005 | Konstantin Aleksandrovich Shestibratov | U 015739-4 | 6030 |
| 140 | 7590 | 03/05/2010 | | |
| LADAS & PARRY LLP 26 WEST 61ST STREET NEW YORK, NY 10023 | | | EXAMINER IBRAHIM, MEDINA AHMED | |
| | | | ART UNIT 1638 | PAPER NUMBER |
| | | | NOTIFICATION DATE 03/05/2010 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nyuspatactions@ladas.com

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/531,769 | Applicant(s) SHESTIBRATOV ET AL. | |
| | Examiner Medina A. Ibrahim | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-32, 35, 41, 43, 45 and 47-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-32, 35, 41, 43, 45 and 47-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 12/10/09 in reply to the Office action 06/10/09 has been entered. Claims 26 is amended. New claims 50-51 are added. Claims 26-32, 35, 41, 43, 45, and 47-51 are pending and are examined.

All previous objections and rejections not set forth have been withdrawn in view of Applicant's amendment to the claims and/or upon further consideration.

Claim Rejections - 35 USC § 112

Claims 26-32, 35, 41, 43, 45, and 47-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26 is indefinite for lacking correlation between the preamble and the last method step. The claim is drawn to a method of producing a transgenic strawberry plant, and the last method step is forming from 2 to 5 next stages explants. The last method step does not produce a transgenic strawberry plant. Clarification is required to more clearly define the metes and bounds of the claim. Dependent claims 27-32, 35, 41, 43, 45, and 47-49 do not obviate the rejection, therefore, are included in the rejection.

Claim 50 is indefinite for lacking correlation between the preamble and the last method step. The claim is drawn to a method of producing a transgenic strawberry plant, and the last method step is transferring the explants onto selection and

Art Unit: 1638

regeneration medium. The last method step does not produce a transgenic strawberry plant. Clarification is required to more clearly define the metes and bounds of the claim.

Claim Rejections - 35 USC § 103

Claims 26-32, 35, 41, 43, 45, and 47-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathews et al (US 5, 750, 870) in view of Dogov et al (Genetics and Breeding for crop quality and Resistance, pp. 165-172 (1999); Applicant's IDS). This rejection is repeated for the reasons of record as set forth in the last Office action of 06/10/09. Applicant's arguments filed 12/10/09 have been fully considered but are not deemed persuasive.

Applicant asserts that the cited references do not teach the claimed stepwise inoculation of explants that lowered the level of necrosis in explants and enhances the efficiency of the method. Applicant relies upon the following points to support this position: firstly, Applicant asserts that in the claimed method, the internal induction process occurring in an explant after wounding is a result of separating an explant from the leaf discs; secondly, the enhanced level of resistance is caused by the use of time intervals between the first and the second steps of separating the explants from each other because during the 1 to 5 days interval one side of the explant is healed by proteins and enzymes induced not only at the site of wounding; and thirdly, the final separation of an explant from a leaf is carried out upon completion of regeneration of the rear side of the explant (response, p.8).

These are not found persuasive for the reasons of record. Mathews et al teach a method of producing a transgenic strawberry plant via *Agrobacterium tumefaciens* using leaf segments as an explant for inoculation and regeneration; co-cultivating the segmented explants with the *Agrobacterium* for 1-3 days; after a stepwise selection process, transgenic plants were quickly established in soil with 100% success as shown in Examples 6-11 and Table 2; columns 23-28. While Mathews et al do not explicitly teach the use of leaf discs as explants, the use of leaf disc as explant for inoculation and regeneration was well established in the prior art as evidenced by Nehra et al cited by Mathews. Nehra et al teach transformation of strawberry and direct shoot regeneration from strawberry leaf discs and efficient regeneration of transgenic redcoat strawberry.

Regarding the reduced level of necrosis as a result of stepwise inoculation procedure, it is noted that Mathews et al states "pure transgenic explants by dividing the regenerated plant shoots into explants and culturing the explants, and verifying that the growth of all explants is resistant to the highest concentration of selective agent used. That is the presence of selective agent there is no necrosis." With regard to the development of efficient strawberry transformation method, Plessis et al teach efficient transformation of strawberry cultivar Selektta using via *Agrobacterium* using explants of leaf pieces from greenhouse plants; said leaf pieces were inoculated with *Agrobacterium* strain containing GUS or PAT gene under the control of 35 CaMV in a binary vector; transformed shoots were produced from media containing 50 mg/l of kanamycin and regenerated to transformed strawberry plant. Applicant shows no

Art Unit: 1638

comparison between what is known in the prior art and the claimed method that shows unexpected results.

Regarding the arguments that during the time interval of 1 to 5 days both sides of the explants “is healed” by induced proteins and enzymes, these limitations are not recited in the rejected claims.

MPEP section 2141 states “the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge. This is so regardless of whether the source of that knowledge and ability was documentary prior art, general knowledge in the art, or common sense. What follows is a discussion of the Graham factual inquiries. The MPEP further states “[p]rior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art. The prior art reference (or references when combined) need not teach or suggest all the claim limitations..... The “mere existence of differences between the prior art and an invention does not establish the invention’s nonobviousness.” *Dann v. Johnston*, 425 U.S. 219, 230, 189 USPQ 257, 261 (1976).

In *KSR, International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385, 1395-97 (2007), the Supreme Court particularly emphasized “the need for caution in granting a patent based on the combination of elements found in the prior art.” It states “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at ___, 82 USPQ2d at 1395.

Art Unit: 1638

The Supreme Court further stated that:

“When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Id.* at ___, 82 USPQ2d at 1396.

“A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton.” *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1397 (2007). “[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.” *Id.* Office personnel may also take into account “the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at ___, 82 USPQ2d at 1396.

See also *United States v. Adams*, . . . [t]he Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.” *Id.* at ___, 82 USPQ2d at 1395”; *Ex parte Kubin*, 83 USPQ2d 1410 (*Bd. Pat. App. & Int.* 2007); and *Ex parte Smith*...USPQ2d-at 20 (*Bd. Pat. App & Interf.* June 25, 2007) (citing *KRS*, 82 USPQ2d at 1396).

Therefore, for all the reasons discussed above and in the last Office action, the rejection is proper.

The above rejection can be obviated by evidence of unexpected results provided in the form of 132 declarations.

Remarks

No Claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571)272-0797. The examiner can normally be reached on M-TH 8:00 am to 5:30 PM, and every other Friday from 8:00 AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAI
3/1/2010

/Medina A Ibrahim/
Primary Examiner, Art Unit 1638